The CliniSense LifeTrack™
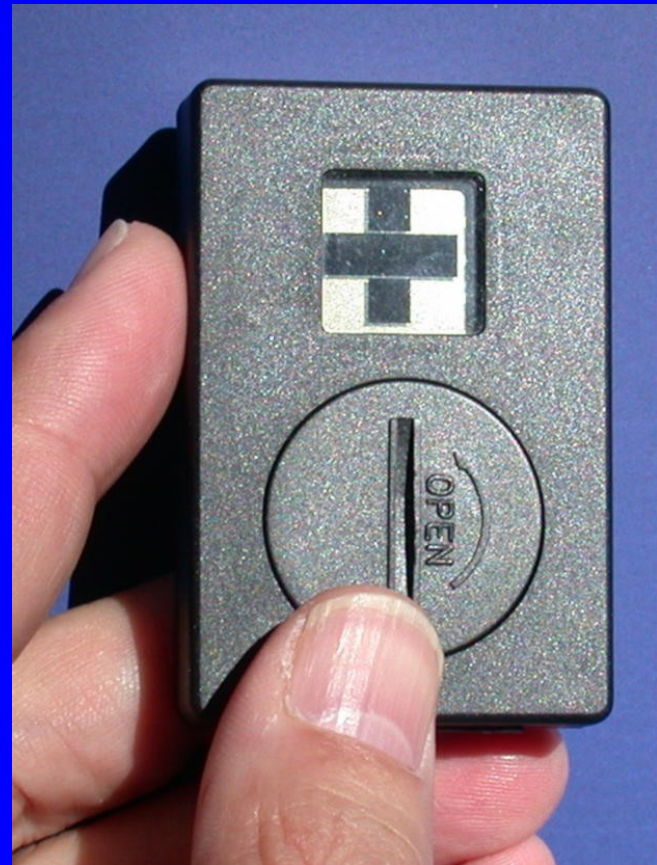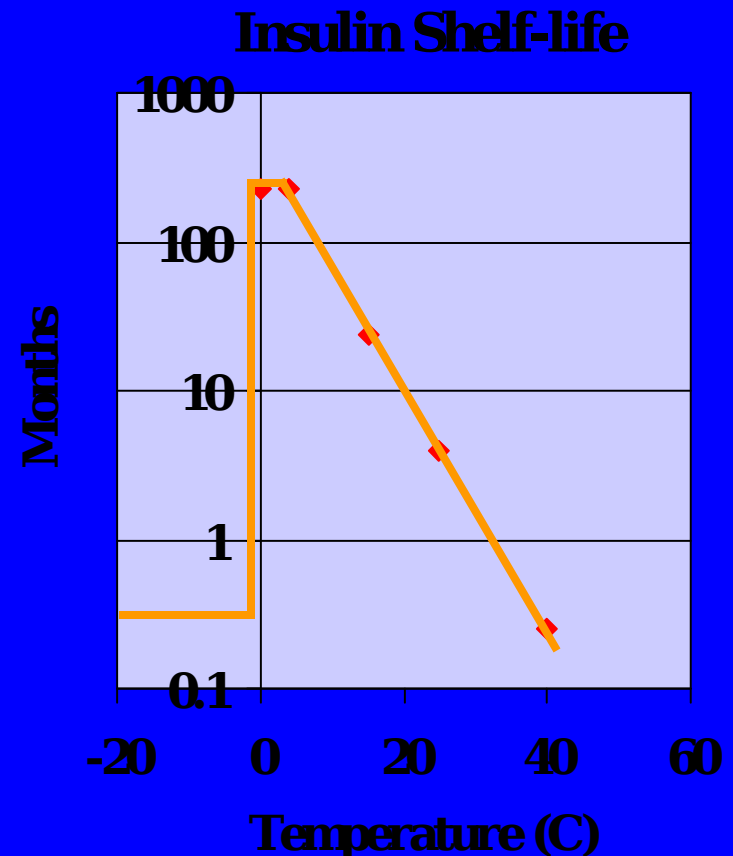
CliniSense Corporation

About CliniSense

- Located in Los Gatos, CA (Silicon Valley)
- Founded in 2001
- Privately funded
- Medical diagnostics and instrumentation background
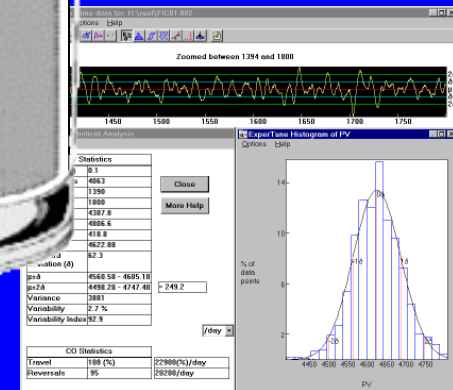- Emphasis on quality and precision

Shelf Life Issues

- Shelf life is determined by both time and temperature
- Most materials deteriorate faster at high temperatures
- Some materials "die quickly" at temperature extremes

Insulin Shelf-life

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The ideal shelf-life indicator

- Is accurate
- Immediately tells if the product is still good
- Has a "gas gauge" to show remaining shelf life
- Can provide a detailed product history record upon request
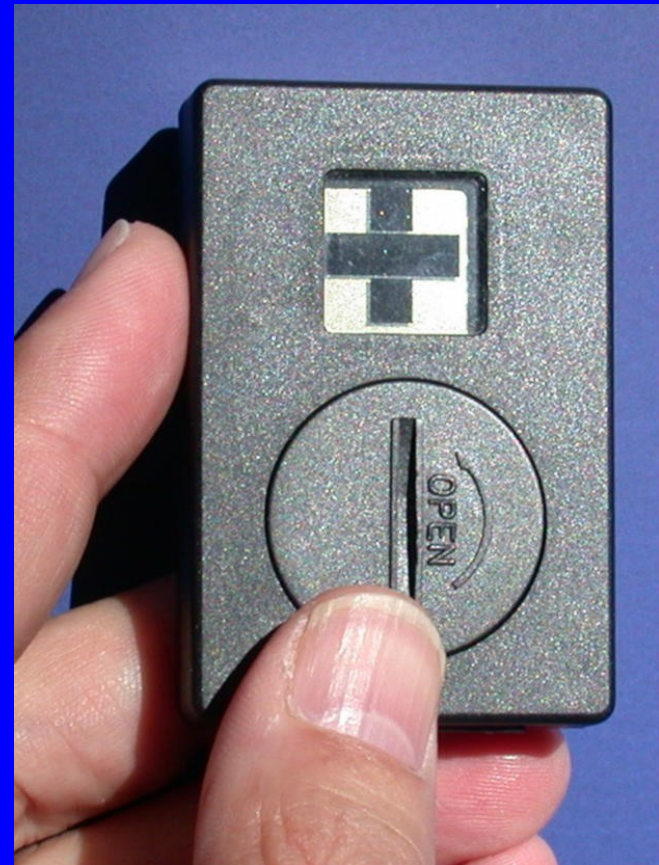
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Previous shelf-life instruments

- Chemical indicators show shelf-life, but are not flexible or accurate
- Electronic temperature loggers are accurate, but don't show shelf-life.
- Temperature alarms only show extreme "out of bounds" conditions

Chemical

Electronic
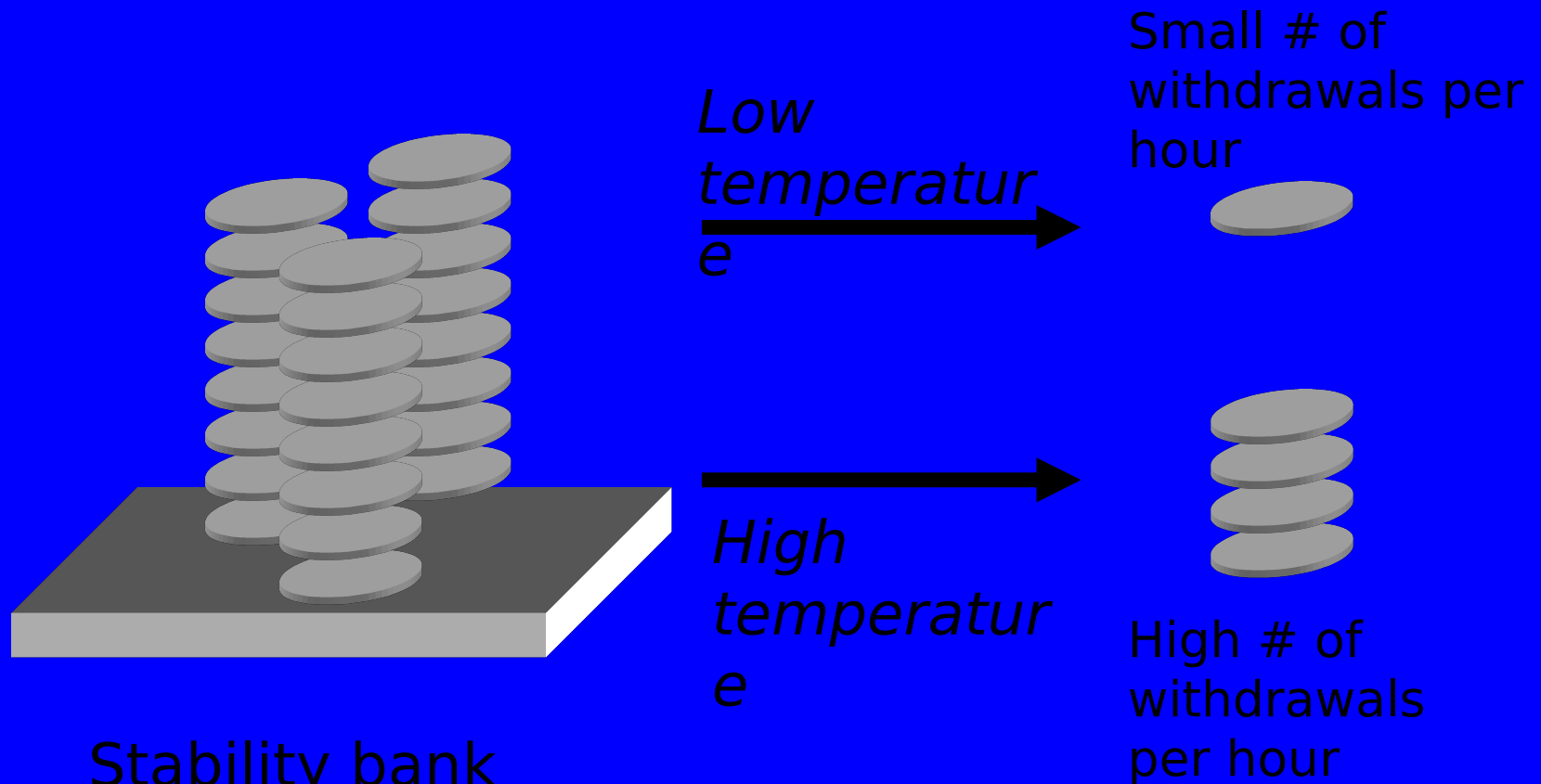
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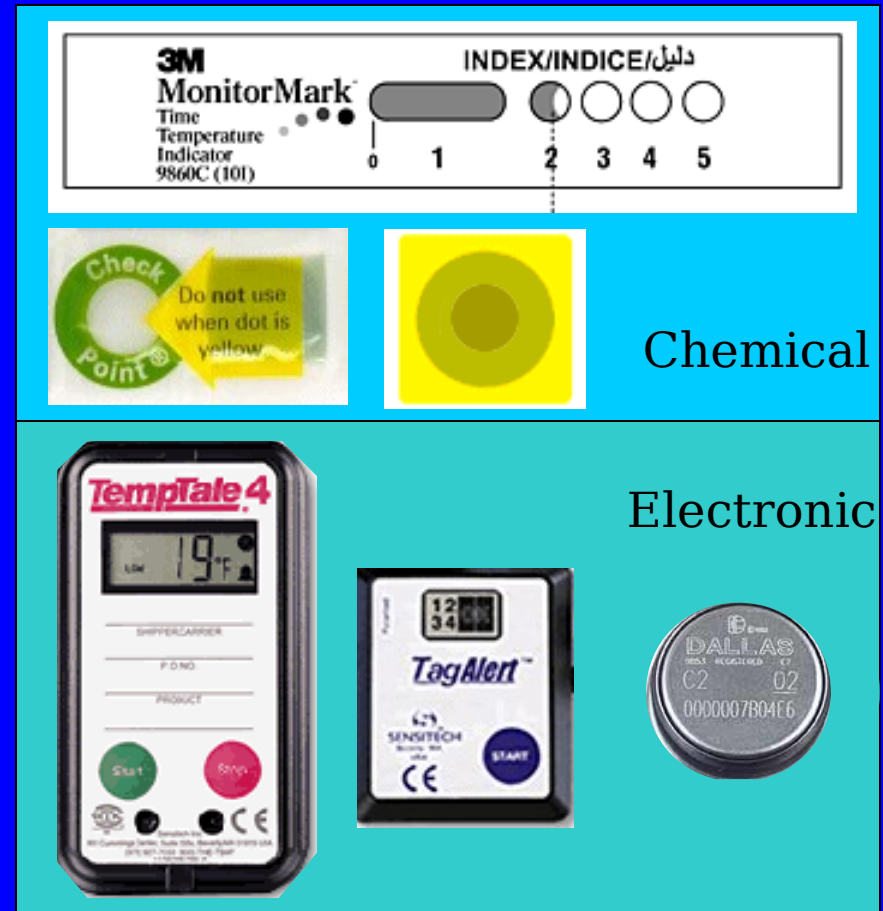
The CliniSense LifeTrack™

- Monitors and analyzes temperature history
- Programmed with a material's sensitivity curve
- Displays remaining shelf-life
- Downloads data to a computer

The stability bank algorithm

Low temperature

Small # of withdrawals per hour

High temperature

High # of withdrawals per hour
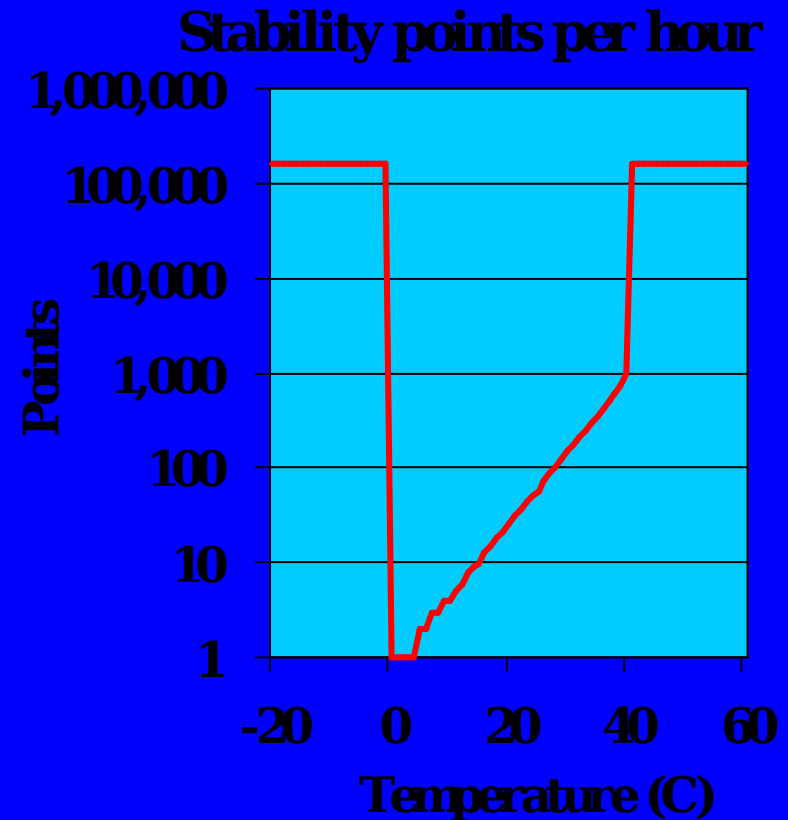
Stability bank "B"

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Stability calculation example

$$B = 165984 - \sum_{0}^{time} P(temperature)$$

Insulin Shelf-life

Stability points per hour
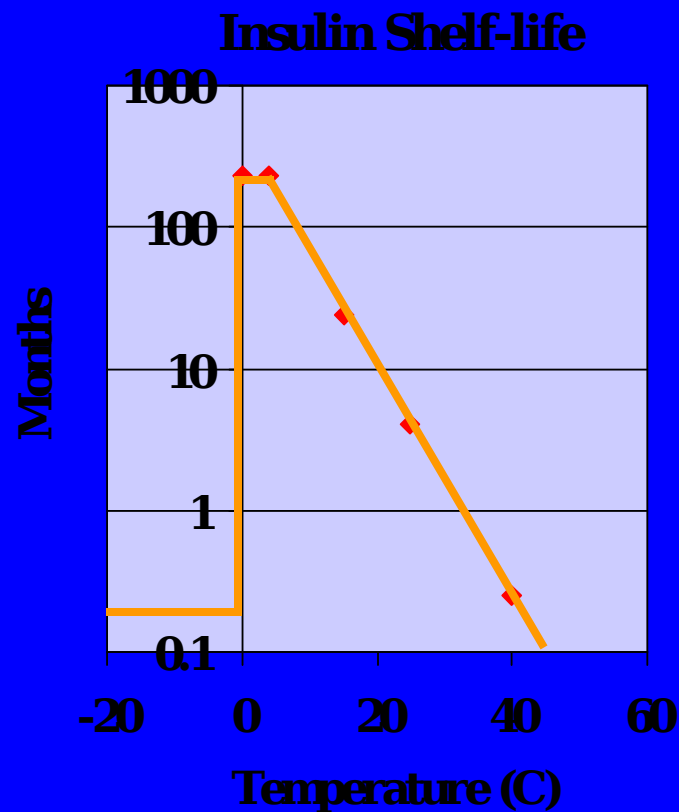
LifeTrack Display

- Shows "+" when product is good, "-" when product has expired

- Lifetime indicator bars decrease as the lifetime is used up

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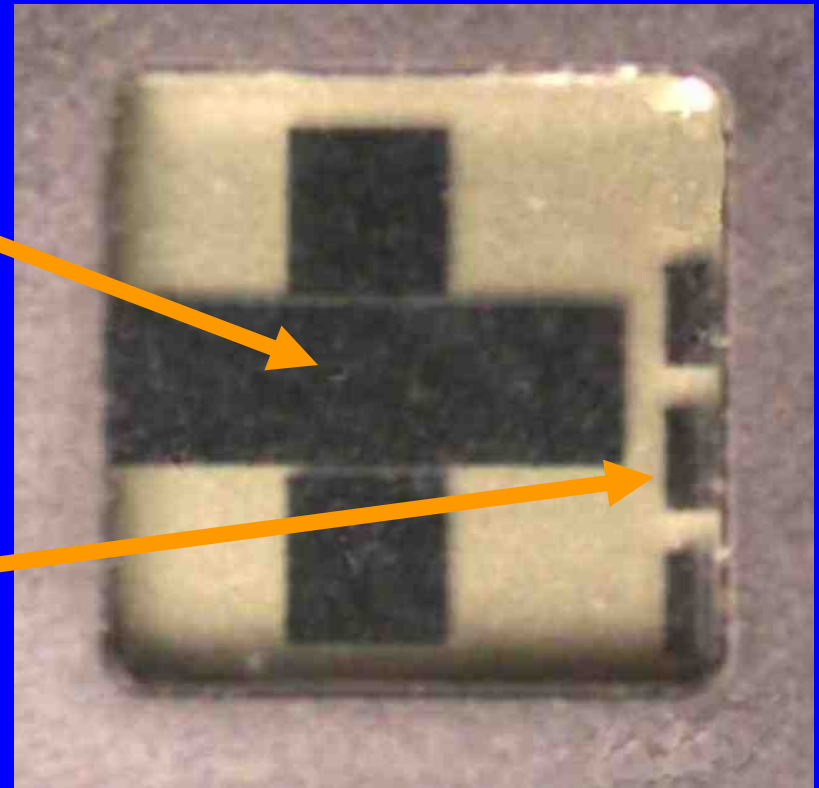
Applications

- Algorithm can track stability ranging from "ice cream" to "rubber tires"
- Medical products & drugs
- Biodefense Diagnostics
- Food
- Chemicals
- Temperature sensitive rubber and plastics

The LifeTrack unit

Thermistor

+/- good bad display

Lifetime bar

Battery door

Infrared LED

Programming & expansion Port

TEST

RESET

OPEN

GLD
LITHIUM BATTERY
CR2032
3V

Battery
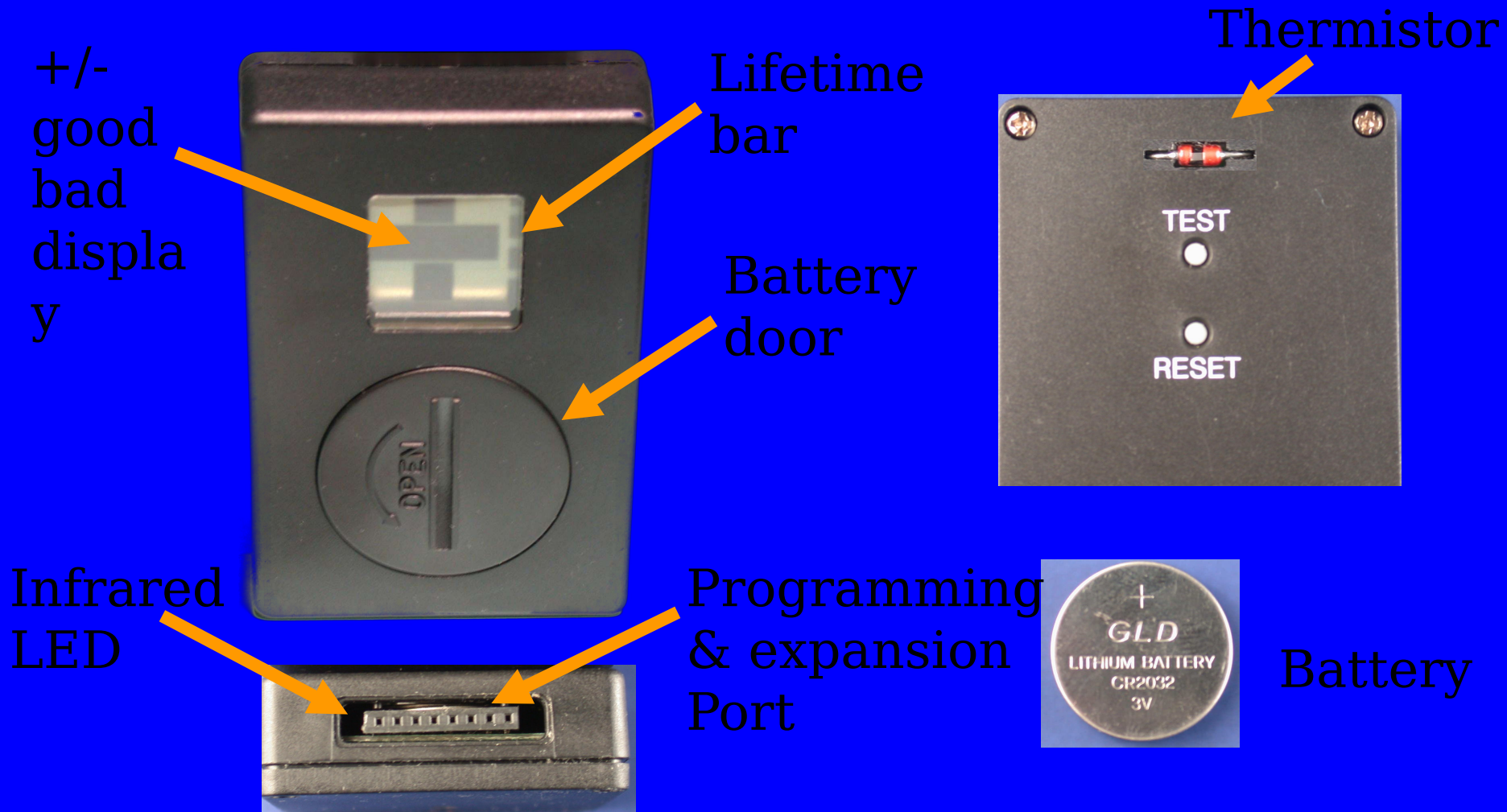
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Data transmission (standard unit)
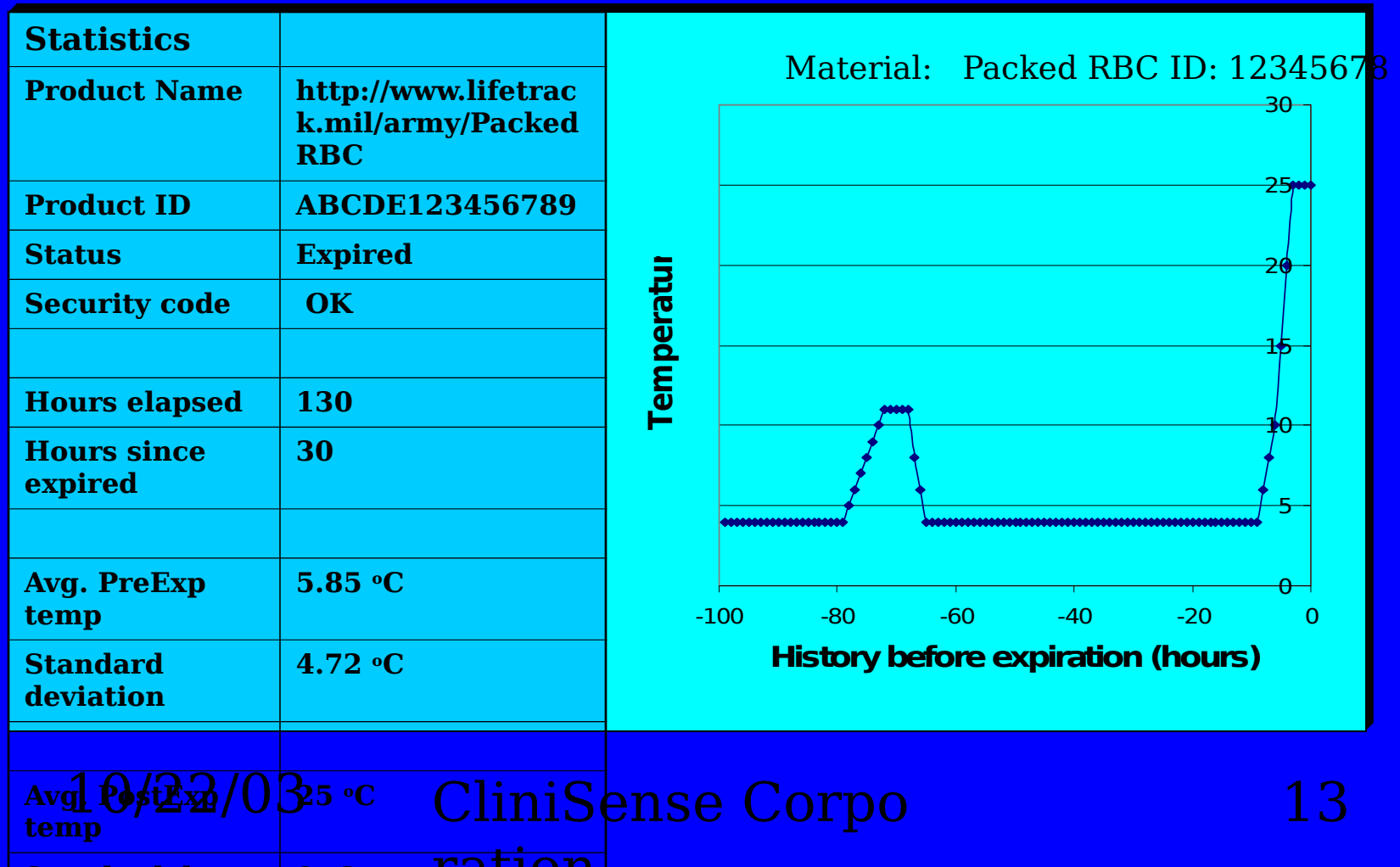
- Infrared link to Optical RS232 cable
- Compatible with Windows & Linux
- Can be interpreted on the spot or directed to a remote web site
- "Open system" users can control data & applications

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Data output example

Statistics	
Product Name	**http://www.lifetrack.mil/army/Packed RBC**
Product ID	**ABCDE123456789**
Status	**Expired**
Security code	**OK**
Hours elapsed	**130**
Hours since expired	**30**
Avg. PreExp temp	**5.85 ºC**
Standard deviation	**4.72 ºC**
Avg. PostExp temp	**25 ºC**

Material: Packed RBC ID: 12345678

Temperature vs History before expiration (hours)

Simple internet connectivity

- Downloaded data pastes directly into a standard web browser address bar
- Data is transferred to remote internet servers, & processed by the standard "CGI GET" protocol
- Data can be stored in any internet server and used as needed

CliniSense - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Search Favorites Media

Address http://www.lifetrack.mil/army/packedrbc/A124569~10AB11~12BC10

Security: Is the data genuine?

- Generates a unique random number when reset
- Number is scrambled (weak encryption) for transmission
- Users can compare beginning number with end number
- If matches, is OK (FDA 21 CFR part 11 compatible)

FRAUD

Accuracy

- Unit designed for multi-point calibration to NIST standards

- Each calibration point requires a separate step

- Two point calibration (0 ^{o}C, 40 ^{o}C) standard to +/- 0.5 ^{o}C

- Additional calibration points on special order
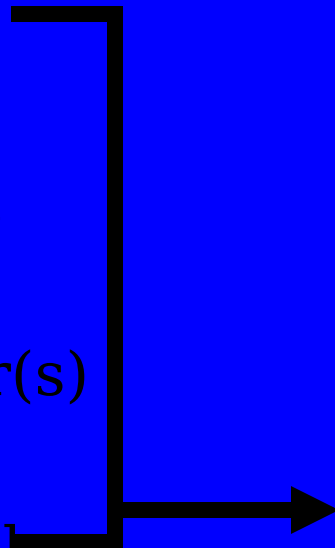
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Expansion port capabilities

- Enables rapid customization, modules developed upon special order:
  - Extra memory
  - RFID radio link
  - Larger battery
  - External sensor(s)
  - Sonic alarm
  - Electrical switch

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Battery life

- Unit uses an ultra-low power microprocessor
- Standard unit uses a CR2032 battery – 2 years
- Custom plug-in expansion battery upon special order
- Custom case with a larger 10 year battery can also be produced (special contract)


Standard CR2032 battery

Cost and Availability

- Basic unit (includes logger, IR output, 2 year battery, 2 point calibration) about $20 in volume

- Programming NRE fee

- Units are reusable

- Timetable
  - Evaluation units 1Q '04
  - Lead-time from PO to production ~2 months

Production capability

- Product based on a Texas Instruments microprocessor
- CliniSense design, IP (patents pending), calibration and temperature programming
- Assembled in China, high volume production facility
- Rapid ramp-up is possible
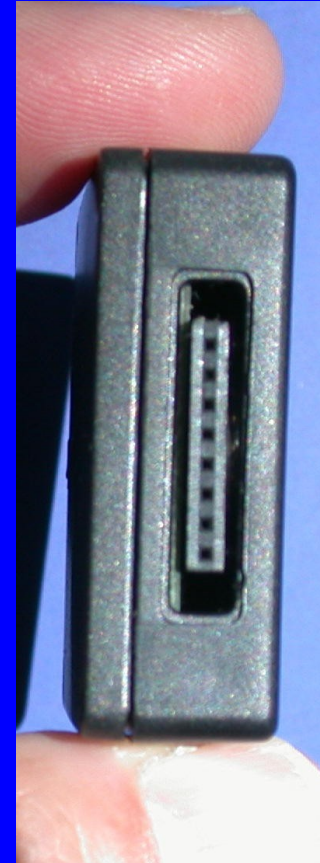
Interested groups include:

- Air Force Battlelabs
- SBCCOM
- USAMMA

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CliniSense Contact Information

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  - DOD CAGE code: 3KCL9; CCR #: WZF974

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